Amendments to the Drawings:

The attached sheet of drawings includes changes to Figure 2. This sheet, which includes corrected version of Figure 2, replaces the original sheet including Figure 2.

Attachment: Replacement Sheet

REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. Claims 1-7 and 9-18 are pending and currently under examination. Without acquiescence or prejudice, claims 1 and 5 are amended to particularly point out and distinctly claim certain embodiments of Applicants' invention, and new claims 19 and 20 are added. No new matter has been added by the amendments. Support for the amendments can be found in the specification as filed, for example, at page 103, lines 4-6; page 105, lines 20-22; page 105, line 30 to page 106, line 2; and Figures 5 and 6.

DRAWINGS

Applicants kindly thank the Examiner for accepting the replacement sheet for Figure 16.

As to the paper identified by the Examiner as a replacement sheet for "Figure 1," Applicants apologize for the confusion and note that this paper was not submitted as a replacement sheet for Figure 1 of the instant application, but was instead submitted as extrinsic evidence to show the sequence homology (or lack thereof) between SEQ ID NO:11 of Asrar *et al.* and the polypeptide encoded by SEQ ID NO:1 of the instant claims.

Further to the above, Applicants submit herewith a replacement sheet for Figure 2 to correct an obvious typographical error, and respectfully request consideration and acceptance of this corrected Figure. As would be obvious to persons skilled in the chemical art, the chemical structure of polyhydroxybutyrate (PHB) at the bottom of original Figure 2 is not only incorrect, but is structurally impossible. For instance, knowing that each C should have 4 bonds, it is obvious that one C has 6 bonds, and another C has only 3 bonds.

Because of this obvious error, Figure 2 has been replaced with a corrected version of this Figure, which provides the correct chemical structure of PHB. In this regard, Applicants note that an amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *See* M.P.E.P. § 2163.07, citing *In re Odd*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). Here, given that the basis for this amendment lies with an obvious typographical

error, which would be apparent to a person skilled in the art based on the well-known chemical structure of PHB, Applicants submit that no new matter has been added by the appropriate correction thereof.

Applicants respectfully request that the Office accept the corrected version of Figure 2.

REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-3, 5-7, and 9-13 stand rejected under 35 U.S.C. § 102(b) for alleged lack of novelty over Asrar *et al.* (U.S. Patent No. 6,091,002). The Examiner asserts that Asrar *et al.* teach a method of making transformed sugarcane plants that produce polyhydroxybutyrate (PHB) using the PHB pathway from *A. eutrophus*, and which utilize polynucleotide sequences that read on the instant SEQ ID NOS:1, 4, and 7.

Applicants traverse this rejection and submit that the instant claims satisfy the requirements of novelty over Asrar *et al.* Nonetheless, without acquiescence, the instant claims as amended herewith relate, in pertinent part, to genetically modified *Saccharum* sp. cells comprising a genetic sequence comprising SEQ ID NO:1,4, and 7, or variants thereof that hybridize thereto under stringent conditions, wherein the *Saccharum* accumulates PHA at about 1.6% of leaf dry-weight, and wherein PHA accumulation does not reduce total sugar content in PHA producing plants as compared to control plants. Also included are methods of use thereof.

It is respectfully submitted that to anticipate the claims, the claimed subject matter must be disclosed in the reference with '***sufficient specificity***' to constitute anticipation under the statute. M.P.E.P. § 2131.03 (emphasis added); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) ("The identical invention must be shown in as ***complete detail*** as is contained in the ... claim.") (emphasis added). Here, Asrar *et al.* fail to disclose each feature of the instant claims with any degree of specificity, let alone with the requisite degree of specificity to be anticipatory under § 102, *i.e.,* in as complete detail as in the claims. For instance, this reference fails to disclose genetically modified *Saccharum* sp. cells that comprise SEQ ID NO:1,4, and 7, and that accumulate PHA at about 1.6% of leaf dry-weight, wherein PHA accumulation does not reduce total sugar content in PHA producing plants as compared to

control plants; a structural feature that is specifically recited in the instant claims. Mainly, because Asrar *et al.* do not in fact describe any experiments on sugarcane, this reference is too limited to describe in complete detail the particular sugarcane cells of the instant claims, in which PHA accumulation is optimized at about 1.6% leaf dry-weight to avoid reducing the total sugar content of these cells, and to minimize effects on agronomic performance (*see, e.g.,* Example 10 at page 105, lines 15-22; and Figure 5 of the specification). Given the deficiencies in Asrar *et al.*, Applicants submit that this reference fails to anticipate the instant claims as amended herewith.

Further, for new claims 19 and 20, Applicants submit that Asrar *et al.* fail to anticipate these claims, mainly because this reference fails to disclose a sugarcane plant that comprises SEQ ID NOS:1, 4, and 7, in which at least one of these nucleotide sequences is operably linked to a maize polyubiquitin (Ubi) promoter. Indeed, Asrar *et al.* contain no mention of maize Ubi promoters in sugarcane cells. Applicants, thus, submit that new claims 19 and 20 satisfy the requirements of novelty over Asrar *et al.*

In view of the amendments and remarks provided herein, Applicants submit that the instant claims are novel over Asrar *et al.*, and respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).

REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-7 and 9-18 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Asrar *et al.* in view of Liebergesell *et al.* (U.S. Patent No. 6,475,734). The Examiner relies on Asrar *et al.* as detailed in the novelty rejection above, but agrees that this reference does not teach sugarcane plants that, in addition to SEQ ID NOS:1, 4, and 7, further comprise a polynucleotide of SEQ ID NOS:19, 28, or 31, or methods of use thereof. The Examiner, however, asserts that Liebergesell *et al.* teach engineering of plants with polynucleotides of SEQ ID NOS:19, 28, or 31 to produce PHBs. The Examiner then asserts that it would have been obvious to further engineer the sugarcane of Asrar *et al.* to incorporate the polynucleotides sequences of Liebergesell *et al.*, since these sequences were known in the art and allegedly identified as being useful for genetically engineering plants to produce biopolymers.

Applicants submit that the Examiner has not established a *prima facie* case of obviousness over the subject matter of the instant independent claims (*e.g.,* claims 1 and 5), let alone over the claims that depend therefrom. *See In re Mayne*, 104 F.3d 1339 (Fed. Cir. 1997) (The USPTO has the burden of showing a *prima facie* case of obviousness). Here, Applicants submit that the cited references fail to teach each feature of the instant independent claims, and further submit that the Examiner has not provided sufficient technical reasoning to support the assertion that persons of ordinary skill in the art would have had an apparent reason to practice the presently claimed subject matter with a reasonable expectation of success. *See KSR v. Teleflex, Inc.,* No 04-1350 at 4, 14 (U.S. Apr. 30, 2007) ("A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art").

The cited references ***in combination*** fail to teach or suggest each feature of the instant claims. For instance, as summarized in the anticipation rejection above, Asrar *et al.* fail to teach or suggest genetically modified *Saccharum* sp. cells that comprise SEQ ID NO:1,4, and 7, and that accumulate PHA at about 1.6% of leaf dry-weight, wherein PHA accumulation does not reduce total sugar content in PHA producing plants as compared to control plants. Indeed, as noted herein, Asrar *et al.* are silent as to the particular genetically modified sugarcane cells of the instant claims, in which PHA accumulation is optimized at about 1.6% leaf dry-weight to avoid reducing the total sugar content of these cells, and to minimize effects on agronomic performance (*see, e.g.,* Example 10 at page 105, lines 15-22; and Figure 5 of the specification). Liebergesell *et al.* fail to remedy the deficiencies in Asrar *et al.*, because this reference likewise fails to teach or suggest the genetically modified *Saccharum* sp. cells of the instant claims, which not only comprise SEQ ID NO:1,4, and 7, but accumulate PHA at about 1.6% of leaf dry-weight, wherein PHA accumulation does not reduce total sugar content in PHA producing plants as compared to control plants. Given the failure of the cited references ***in combination*** to fairly teach or suggest each feature of the instant claims, it is respectfully submitted that these references fail to provide a requisite element of a *prima facie* case of obviousness.

Further, for new claims 19 and 20, Applicants submit that Asrar *et al.* fail to teach or suggest each feature of these claims, mainly because this reference fails to disclose a

sugarcane plant that comprises SEQ ID NOS:1, 4, and 7, in which at least one of these nucleotide sequences is operably linked to a maize polyubiquitin (Ubi) promoter. Indeed, Asrar *et al.* contain no mention of maize Ubi promoters in sugarcane cells. Liebergesell *et al.* fail to remedy the deficiencies in Asrar *et al.*, because this reference similarly fails to fairly teach or suggest the use of a maize Ubi promoter to stably express transgenes in sugarcane, as presently claimed. Given the failure of the cited references in combination to teach or suggest each feature of new claims 19 and 20, Applicants submit that these claims satisfy the requirements of non-obviousness over the combination of Asrar *et al.* and Liebergesell *et al.*

The cited references in combination also fail to provide any apparent reason to practice the presently claimed subject matter with a reasonable expectation of success. Mainly, given that these references fail to teach or suggest each feature of the instant claims, even if persons skilled in the art at the time of invention combined these references, then they would not have arrived at the presently claimed sugarcane plants and cells. Instead, such persons would have had to embark on a whole new endeavour, such as by successfully and stably transforming sugarcane with multiple (*i.e.,* 3 or more) transgenes, and optimizing the accumulation of PHA to about 1.6% leaf dry-weight to avoid reducing the total sugar content of these cells, thereby minimizing the potentially adverse effects of PHA production on agronomic performance. Neither Asrar *et al.* nor Liebergesell *et al.* provide a reasonable expectation of success in this endeavour, one that is fraught with technical difficulties and uncertainties. Indeed, the mere mention of sugarcane in the methods of Asrar *et al.* is speculative and unsupported by any empirical evidence on the successful cloning of such plants, let alone with multiple PHA-producing transgenes. The mere mention of sugarcane in Liebergesell *et al.* as one member of a laundry list of plants is also speculative, and likewise unsupported by sufficient evidence to provide a reasonable expectation of success in an uncertain endeavour. As previously made of record, it is kindly submitted that assertions of obviousness cannot be based on such speculative and unsupported statements, but must instead be based on some rational underpinning. By failing to provide any tangible, technical bases to reasonably expect the successful production of PHAs in sugarcane plants, specifically, these references fail to establish a reasonable expectation of success in arriving at the presently claimed subject matter.

Further, Applicants respectfully disagree with the Examiner's discussion on gene silencing (*see* the Action, page 4). For instance, the Examiner alleges that gene silencing would not have been expected to occur in sugarcane, at least with respect to the instant bacterial sequences. Specifically, the Examiner asserts that gene silencing was known to occur when multiple transgenes are either identical to each other, or represent endogenous plant genes, neither of which is the case here. However, it is kindly submitted that gene silencing in plants such as sugarcane is not so limited, and at the time of filing would have been expected to affect other foreign sequences, including bacterial DNA sequences, as here (*see, e.g.,* Matzke *et al.*, *Plant Mol Biol.* 43:401-15, 2000, abstract submitted herewith). Indeed, even today, and even using sugarcane specific promoters, persons skilled in the art regularly encounter problems with the unpredictable onset of gene silencing in sugarcane, which especially limits transgene activity in regenerated plants (*see, e.g.,* Mudge *et al.*, *Planta*. 229:549-58, 2009, abstract submitted herewith), such as those of the instant claims. Hence, absent further evidence, the mere speculative inclusion of sugarcane in Asrar *et al.* or Liebergesell *et al.* does not change this expectation, especially since these references provide no tangible evidence of successful sugarcane transformation and stable expression of a single transgene, let alone with three or more separate transgenes. As previously made of record, Applicants submit that persons skilled in the art at the time of invention would have had no reasonable expectation of success in transforming sugarcane with multiple (*i.e.,* 3 or more) transgenes, and relying on stable expression of those transgenes to produce PHAs in sugarcane plants, as presently claimed. Hence, Applicants submit that the Examiner has not established a *prima facie* case of obviousness over the instant claims.

Absent Applicants' own teachings and results, persons skilled in the art at the time of filing would not have predicted or reasonably expected from the cited references to be capable of successfully transforming a species of *Saccharum* with the specific polynucleotides of SEQ ID NOS:1, 4, and 7, including those that hybridize to their complements under stringent conditions, in addition to at least one of the polynucleotides of SEQ ID NOS: 19, 28, or 31. Given the deficiencies in the cited references, mainly with regard to relying on the combination of these sequences to produce PHAs in sugarcane at about 1.6% of leaf dry-weight, wherein

PHA accumulation does not reduce total sugar content in PHA producing plants as compared to control plants, and even assuming that an analysis of obviousness is "in a sense necessarily a reconstruction based upon hindsight reasoning" (*see* the Action, page 5), Applicants can only believe that the Examiner relies ***impermissibly*** on hindsight in asserting that the instant claims are obvious.

In view of the remarks and evidence provided herein, Applicants submit that the instant claims satisfy the requirements of non-obviousness over the cited references, and respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Applicants believe that all of the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/William T. Christiansen/
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WTC:jto/rp

Enclosures:

Replacement Sheet for Figure 2
Matzke *et al.*, *Plant Mol Biol.* 43:401-15, 2000, abstract.
Mudge *et al.*, *Planta*. 229:549-58, 2009, abstract.

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